REMARKS

Claim Amendments

Claims 1, 2, 4 -17 and 19-24 are currently pending.

Claim 1, 4, 6 - 9 and claim 12 are currently amended.

No new matter has been introduced.

Oath Declaration

The Examiner has noted that the Applicant has not complied with the requirements of 37 CFR 1.63(c), since none of the oath, declaration, or application data sheet acknowledge the filing of any foreign applications or US applications.

Accordingly, the Applicant has sent a new declaration for signature to the inventor, which will be forwarded to the Patent Office upon receipt.

Claim Rejections

Rejections Under 35 U.S.C. §112

1.0 ***Claims 1-11 and 23 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.***

Claim 1 recites at least one springy and elongate rod. However, the Examiner states that the specification does not disclose a springy rod attached to a balloon.

Applicant has amended claim 1 to recite "at least one resilient elongate rod, attached to said balloon body". Figure 10 shows a balloon that is attached to "expansion rods" (page 20, lines 16-20). The limitation for a resilient rod is fully supported by the specification.

Rejections Under 35 U.S.C. §102

2.0 ***Claims 1 -11 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Klein (US 5,863,284).***

Klein teaches a device for radiation treatment of an internal body organ. The device comprises a radiation emitting sleeve catheter (RESC) having a proximal portion (14), a central portion (16), and a distal portion (18). The distal portion includes axial slits which allow the distal portion to be radially expanded to engage the walls of a blood vessel. The distal portion further includes a plurality of outside lumens 21, into which a plurality of elongate radioactive elements (30) are disposed. In one embodiment, additional metal bars may also be placed in the lumens of the distal portion, in order to stiffen the distal portion. In operation, a balloon (32) is introduced via a port (24) in the central portion. The balloon is advanced along the catheter until it is disposed within the distal portion. Inflation of the balloon causes the axial slits to radially expand, such that the radioactive elements engage the blood vessel wall.

The Examiner suggests that Klein et al. teaches a balloon catheter attached to rods (18) that conform to a surface of the balloon. Applicant respectfully disagrees. In view of the amendment to claim 1, Applicant submits that the teachings of Klein do not anticipate claim 1 as suggested by the Examiner. Klein does not teach a flow reducing implant, in contrast, Klein teaches a device for radiation treatment that slides over the outer surface of a balloon catheter, where the balloon is used to cause expansion of the radial slits of the radiation device thereby moving the radioactive elements to a position where they engage a blood vessel wall. Klein does not teach or suggest an intra-vascular balloon for adjusting the configuration of a flow reducing implant, nor does Klein teach or suggest an intra-vascular balloon applying radially outward pressure to a flow reducing implant for adjusting the configuration of the flow reducing implant. The amendments to claim 1 are fully supported by the specification, specifically in paragraphs [0129] – [0132].

In view of the above comments, Applicant submits that claim 1 is not anticipated by Klein et al.. Further, as claims 2 -11 and 23 depend from claim 1, each of these claims is also not anticipated by Klein et al..

3.0 ***Claims 12-16, 21 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kavteladze et al. (US 5,683,411).***

Kavteladze et al. teaches a number of vascular implants. One vascular implant, for use as a vessel occlusion device, comprises two coaxial interconnected bodies of revolution (10, 11), each defined by wires (12) forming hexagonal cells, joined by a flexible link 15 and an elastic occlusion membrane 16, formed of an impermeable material, disposed at the apices (13) of the two bodies.

The Examiner suggests that Kavteladze et al. teaches a flexible band (16) having a diameter suitable for implantation in a blood vessel and a plurality of elongate axial elements (12) mounted on an outer surface of the band. Applicant respectfully disagrees. The axial elements of Kavteladze et al. are not mounted on an outer surface of the band as taught by the present invention, instead they are mounted on an inner surface. The aperture of the band of both Kavteladze et al. and the present invention allows for both an outer surface and an inner surface of the band to be defined. The outer surface of the band is proximal to the wall of the blood vessel. The axial elements of Kavteladze et al. are put into place within the band's aperture and are therefore mounted on the inner surface of the band.

In view of the above comments, Applicant submits that claim 12 is not anticipated by Kavteladze et al.. Further, as claims 13-16 and 22 depend from claim 12, each of these claims is also not anticipated by Kavteladze et al..

4.0 ***Claims 12, 21 and 22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Morris et al. (US 2004/0158280).***

Morris et al. teaches a proximal actuator which is operable with various medical devices, which have a tube or wire axially moveable with respect to another tube or wire. The actuator includes frame struts and a perforated filter material attached to the frame struts, thereby forming a frusto-conical structure. The filter material 32 is typically PET having perforations formed therein.

The Examiner suggests that Morris et al. teaches a filter material made of PET, and further that because PET varies from semi-rigid to rigid that a semi-rigid filter as taught in Morris overlaps the claimed flexible band. Applicant respectfully disagrees.

Amended claim 12 recites "a flexible band comprising a resilient material". A person skilled in the art would understand that a flexible resilient band would be constructed of a material capable of absorbing and storing energy when the material is deformed elastically and then, upon unloading to have this energy recovered, for example a shape memory material. Moreover, a person skilled in the art would understand that PET, or Polyethylene terephthalate, is a thermoplastic polymer resin of the polyester family and is often used in the making of synthetic fibers; beverage, food and other liquid containers; thermoforming applications; and engineering resins. PET can be semi-rigid to rigid, depending on its thickness, and is very lightweight. It is strong and impact-resistant. Impact resistance is generally understood to be the resistance of a material to fracture when stressed as well as the ability to absorb energy up until failure. While PET has a strong impact-resistance, the flexible band of the present invention comprises a resilient material, which simply deforms as opposed to ruptures on the application of stress.

In view of the above comments, Applicant submits that claim 12 is not anticipated by Morris et al.. Further, as claims 21 and 22 depend from claim 12, each of these claims is also not anticipated by Morris et al.

5.0 ***Claims 17, 19, 20 and 24 are rejected under 35 U.S.C. § 103(a) as being anticipated by Ruiz (US 6,120,534).***

Ruiz teaches a stent (10) to be implanted in the pulmonary artery. The stent is formed of an expandable mesh (16) having lobed or conical portions (11, 12) joined by a constricted region (13). At least the interior surfaces (14) of the stent are covered with an elastomeric biocompatible material (15). The stent regulates blood flow by restricting it to a degree.

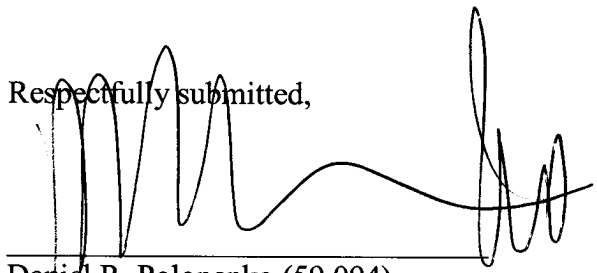
The Examiner suggests that it would have been obvious to restrict the cross section of the constricted region (13) of Ruiz to substantially block all blood flow and for the diameter of the constricted region to be sized for passage of only a guide wire. Applicant respectfully disagrees.

Ruiz does not teach or suggest any specific dimensions for the diameter of the constricted region, nor does Ruiz teach a specific differential between the diameter of the lobed portion and the diameter of the constricted region. Ruiz states in column 4, lines 60-67 that after insertion of the stent, the patient is monitored to assess whether the blood supply to the lungs is adequate through the constricted region (13) at its maximum degree of flow constriction. However, Ruiz does not teach or suggest a value for the maximum degree of flow constriction. Further, Ruiz does not teach or suggest a stent sized for blockage of substantially all blood-flow therethrough, instead Ruiz teaches that a degree of flow is needed in order to ensure an adequate blood supply to the lungs.

In view of the above comments, Applicant submits that claim 17 is not anticipated by Ruiz. Further, as claims 19, 20 and 24 depend from claim 17, each of these claims is also not anticipated by Ruiz.

In view of the above amendments and comments, the applicant submits that pending claims 1, 2, 4 -17 and 19-24 are patentable. Favorable reconsideration and allowance of this application are respectfully requested.

Respectfully submitted,

By: 

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